



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/766,403

01/27/2004

Luiz Belardinelli

02-479-E

3369

20306

7590

04/01/2009

MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER

CRANE, LAWRENCE E

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

04/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/766,403	Applicant(s) BELARDINELLI ET AL.	
	Examiner Lawrence E. Crane	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 30, 2008 (amendment).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74,77 and 79-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74,77 and 79-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/30/2008</u> | 6) <input type="checkbox"/> Other: _____ |

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Applicant's arguments filed November 30, 2008 have been fully considered but they are not persuasive.

Applicant has acknowledged the above request and indicated that formal drawings would be submitted after a finding allowability.

Claims **1-63** were previously cancelled, claims **64-73, 75, 76 and 78** have been newly cancelled, claims **74, 77, 79, 80 and 83** have been amended, the disclosure has been amended as requested, and no new claims have been added as per the amendment filed October 30, 2008. One additional or supplemental Information Disclosure Statements (1 IDS) filed October 30, 2008 has been received with copies of all non-US patent documents and made of record.

Claims **74, 77 and 79-89** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **74, 77 and 79-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-11** of copending Application No. **11/253,322** in view of **Swinyard et al. (II)** (PTO-892 ref. **S**) and further in view of **Harvey** (PTO-892 ref. **T**).

In the portion of the ‘**322** application at pages 8-9, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including “buffers.” This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The ‘**322** reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al. (II)** reference (PTO-892 ref. **S**) is a very well known in the art source of guidance concerning how to prepare a pharmaceutical composition. In this Chapter of Remington’s Pharmaceutical Sciences applicant will find the pharmaceutical excipients EDTA (p. 1321, col. 2), various grades of water (pages 1300-1301 et seq), and propylene glycol (page 1317). In addition in **Harvey et al.** (PTO-892 ref. **T**) applicant will find at page 821 the buffer sodium phosphate and a brief description of how to prepare buffers therefrom.

In light of the generic teaching of “buffered” CVT-3146 compositions in the ‘**322**’ application and the teachings of **Swinyard et al. (II)**, development of the specific examples at page 37 herein would have been obvious variations of the buffers taught generically by the ‘**322**’ application in order to obtain a pH 6-to-pH 8 buffered composition comprising CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the ‘**322**’ application teaches buffered pharmaceutical compositions and the **Swinyard et al. (II)** and **Harvey** references disclose the specific excipients and buffers claimed herein and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **64-89** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendments.

Claims **74, 77 and 79-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-4, 6-18 and 21-30** of copending Application No. **10/629,368** in view of **Swinyard et al.** (PTO-892 ref. **S**) and further in view of **Harvey** (PTO-892 ref. **T**).

In the portion of the '**368** application at page 10, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including "buffers." This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The '**368** reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al. (II)** reference (PTO-892 ref. **S**) is a very well known in the art source of guidance concerning how to prepare a pharmaceutical composition. In this Chapter of Remington's Pharmaceutical Sciences applicant will find the pharmaceutical excipients EDTA (p. 1321, col. 2), various grades of water (pages 1300-1301 et seq), and propylene glycol (page 1317). In addition in **Harvey et al.** (PTO-892 ref. **T**) applicant will find at page 821 the buffer sodium phosphate and a brief description of how to prepare buffers therefrom.

In light of the generic teaching of "buffered" CVT-3146 compositions in the '**368**' application and the teachings of **Swinyard et al. (II)**, development of the specific examples at

page 37 herein would have been obvious variations of the buffers taught generically by the ‘368 application in order to obtain a pH 6-to-pH 8 buffered composition comprising CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the ‘368 application teaches buffered pharmaceutical compositions and the **Swinyard et al. (II)** and **Harvey** references disclose the specific excipients and buffers claimed herein and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant’s arguments with respect to claims **64-89** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant’s amendments.

Claims **74, 77 and 79-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over allowed claims **11, 14-27, 29-30, 34 and 36-37** of copending allowed Application No. **11/070,768** in view of **Swinyard et al. (II)** (PTO-892 ref. **S**) and further in view of **Harvey** (PTO-892 ref. **T**).

In the portion of the ‘768 application at pages 12-13, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including “buffers.” This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The ‘768 reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al. (II)** reference (PTO-892 ref. **S**) is a very well known in the art source of guidance concerning how to prepare a pharmaceutical composition. In this Chapter of Remington's Pharmaceutical Sciences applicant will find the pharmaceutical excipients EDTA (p. 1321, col. 2), various grades of water (pages 1300-1301 et seq), and propylene glycol (page 1317). In addition in **Harvey et al.** (PTO-892 ref. **T**) applicant will find at page 821 the buffer sodium phosphate and a brief description of how to prepare buffers therefrom.

In light of the generic teaching of "buffered" CVT-3146 compositions in the '**768** application and the teachings of **Swinyard et al. (II)**, development of the specific examples at page 37 herein would have been obvious variations of the buffers taught generically by the '**768** application in order to obtain a pH 6-to-pH 8 buffered composition comprising CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the '**768** application teaches buffered pharmaceutical compositions and the **Swinyard et al. (II)** and **Harvey** references disclose the specific excipients and buffers claimed herein and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

Applicant's arguments with respect to claims **64-89** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendments.

Claims **74, 77 and 79-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **5-8 and 10-22** of U. S. Patent **7,183,264** (PTO-892 ref. **B**) in view of **Swinyard et al.** (PTO-892 ref. **R**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging, the only difference being the presence of a different buffer.

In the portion of the ‘264 patent beginning at column 15, line 32, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including “buffers.” This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The ‘264 patent reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al. (II)** reference (PTO-892 ref. S) is a very well known in the art source of guidance concerning how to prepare a pharmaceutical composition. In this Chapter of Remington’s Pharmaceutical Sciences applicant will find the pharmaceutical excipients EDTA (p. 1321, col. 2), various grades of water (pages 1300-1301 et seq), and propylene glycol (page 1317). In addition in **Harvey et al.** (PTO-892 ref. T) applicant will find at page 821 the buffer sodium phosphate and a brief description of how to prepare buffers therefrom.

In light of the generic teaching of “buffered” CVT-3146 compositions in the ‘264 patent and the teachings of **Swinyard et al. (II)**, development of the specific examples at page 37 herein would have been obvious variations of the buffers taught generically by the ‘264 patent in order to obtain a pH 6-to-pH 8 buffered composition comprising CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the ‘264 patent teaches buffered pharmaceutical compositions and the **Swinyard et al. (II)** and **Harvey** references disclose the specific excipients and buffers claimed herein and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

Applicant’s arguments with respect to claims 64-89 have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant’s amendments.

Claims **74, 77 and 79-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **10-24** of U. S. Patent **7,144,872** (PTO-1449 (#5) ref. **E5**) in view of **Swinyard et al.** (PTO-892 ref. **R**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging, the only difference being the presence of a different buffer.

In the portion of the **'872** patent beginning at column 15, line 30, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including "buffers." This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The **'872** patent reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al. (II)** reference (PTO-892 ref. **S**) is a very well known in the art source of guidance concerning how to prepare a pharmaceutical composition. In this Chapter of Remington's Pharmaceutical Sciences applicant will find the pharmaceutical excipients EDTA (p. 1321, col. 2), various grades of water (pages 1300-1301 et seq), and propylene glycol (page 1317). In addition in **Harvey et al.** (PTO-892 ref. **T**) applicant will find at page 821 the buffer sodium phosphate and a brief description of how to prepare buffers therefrom.

In light of the generic teaching of "buffered" CVT-3146 compositions in the **'872** patent and the teachings of **Swinyard et al. (II)**, development of the specific examples at page 37 herein would have been obvious variations of the buffers taught generically by the **'872** patent in order to obtain a pH 6-to-pH 8 buffered composition comprising CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the **'872** patent teaches buffered pharmaceutical compositions and the **Swinyard et al. (II)** and **Harvey** references disclose the specific excipients and buffers claimed herein and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

Applicant's arguments with respect to claims **64-89** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendments.

Claims **74, 77 and 79-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **9, 10, 11 and 16** of U. S. Patent No. **6,642,210** (PTO-1449 (#3) ref. **A15**) in view of **Swinyard et al.** (PTO-892 ref. **R**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging, the only difference being the presence of a different buffer.

In the portion of the '**210** patent beginning at column 16, line 5, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including "buffers." This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The '**210** patent reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al. (II)** reference (PTO-892 ref. **S**) is a very well known in the art source of guidance concerning how to prepare a pharmaceutical composition. In this Chapter of Remington's Pharmaceutical Sciences applicant will find the pharmaceutical excipients EDTA (p. 1321, col. 2), various grades of water (pages 1300-1301 et seq), and propylene glycol (page 1317). In addition in **Harvey et al.** (PTO-892 ref. **T**) applicant will find at page 821 the buffer sodium phosphate and a brief description of how to prepare buffers therefrom.

In light of the generic teaching of "buffered" CVT-3146 compositions in the '**210** patent and the teachings of **Swinyard et al. (II)**, development of the specific examples at page 37

herein would have been obvious variations of the buffers taught generically by the ‘**210** patent in order to obtain a pH 6-to-pH 8 buffered composition comprising CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the ‘**210** patent teaches buffered pharmaceutical compositions and the **Swinyard et al. (II)** and **Harvey** references disclose the specific excipients and buffers claimed herein and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

Applicant’s arguments with respect to claims **64-89** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant’s amendments.

Claims **74, 77 and 79-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **9-13** of U. S. Patent No. **6,403,567** (PTO-1449 (#1) ref. **A13**) in view of **Swinyard et al.** (PTO-892 ref. **R**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment in both applications involve administration of the identical active ingredient, CVT-3146, to induce coronary vasodilation for the purpose of cardiac blood flow imaging, the only difference being the presence of a different buffer.

In the portion of the ‘**567** patent beginning at column 14, line 58, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including “buffers.” This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The ‘**567** patent reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al. (II)** reference (PTO-892 ref. **S**) is a very well known in the art source of guidance concerning how to prepare a pharmaceutical composition. In this Chapter of Remington's Pharmaceutical Sciences applicant will find the pharmaceutical excipients EDTA (p. 1321, col. 2), various grades of water (pages 1300-1301 et seq), and propylene glycol (page 1317). In addition in **Harvey et al.** (PTO-892 ref. **T**) applicant will find at page 821 the buffer sodium phosphate and a brief description of how to prepare buffers therefrom.

In light of the generic teaching of "buffered" CVT-3146 compositions in the '**567** patent and the teachings of **Swinyard et al. (II)**, development of the specific examples at page 37 herein would have been obvious variations of the buffers taught generically by the '**567** patent in order to obtain a pH 6-to-pH 8 buffered composition comprising CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the '**567** patent teaches buffered pharmaceutical compositions and the **Swinyard et al. (II)** and **Harvey** references disclose the specific excipients and buffers claimed herein and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

Applicant's arguments with respect to claims **64-89** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendments.

Claims **74, 77 and 79-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **26-44** of U. S. Application No. **11/588,834** (PTO-1449 (#5) ref. **D5**) in view of **Swinyard et al.** (PTO-892 ref. **R**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment wherein either coronary vasodilation, or increased coronary blood flow made possible by said vasodilation, is induced by administration of the identical active ingredient, CVT-3146 in the presence of a small amount of a different buffer.

In the portion of the ‘834 application at page 20, the pharmaceutical compositions comprising CVT-3146 are defined with carriers including “buffers.” This application is also directed to the administration of the buffered CVT-3146 compositions to induce a brief vasodilation of cardiac vasculature for the purpose of permitting concomitant contrast agent administration and simultaneous visualization of possible blockages therein.

The ‘834 reference does not specify or otherwise teach buffered compositions comprising CVT-3164 with a pH in the range of pH 8.5 and 10.

The **Swinyard et al. (II)** reference (PTO-892 ref. S) is a very well known in the art source of guidance concerning how to prepare a pharmaceutical composition. In this Chapter of Remington’s Pharmaceutical Sciences applicant will find the pharmaceutical excipients EDTA (p. 1321, col. 2), various grades of water (pages 1300-1301 et seq), and propylene glycol (page 1317). In addition in **Harvey et al.** (PTO-892 ref. T) applicant will find at page 821 the buffer sodium phosphate and a brief description of how to prepare buffers therefrom.

In light of the generic teaching of “buffered” CVT-3146 compositions in the ‘834 patent and the teachings of **Swinyard et al. (II)**, development of the specific examples at page 37 herein would have been obvious variations of the buffers taught generically by the ‘834 patent in order to obtain a pH 6-to-pH 8 buffered composition comprising CVT-3146.

One having ordinary skill in the art would have been motivated to combine these references because the ‘834 patent teaches buffered pharmaceutical compositions and the **Swinyard et al. (II)** and **Harvey** references disclose the specific excipients and buffers claimed herein and their incorporation into pharmaceutical compositions.

Therefore, the instant claimed buffered pharmaceutical compositions and related method of inducing brief coronary vasodilation by the administration of said compositions would have been obvious to one of ordinary skill in the art having the above cited application and the above cited reference before him at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims **64-89** have been considered but are moot in view of the new grounds of rejection. This new ground of rejection was necessitated by applicant's amendments.

Claims **74, 77 and 79-89** of this application conflict with claims **1-11** of copending Application No. **11/253,322**, claims **1-4, 6-18 and 21-30** of copending Application No. **10/629,368**, allowed claims **11, 14-27, 29-30, 34 and 36-37** of copending allowed Application No. **11/070,768**, and claims **26-44** of U. S. Application No. **11/588,834**. 37 C.F.R. §1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

Applicant is respectfully requested to supply the serial numbers of any other US Patents assigned to CV Therapeutics and any other US Patent applications assigned to CV Therapeutics that claim subject matter overlapping with instant claims **74, 77 and 79-89**.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX

(unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
02/17/2009

/Lawrence E. Crane/

Primary Examiner, Art Unit 1623

L. E. Crane
Primary Patent Examiner
Technology Center 1600